

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A medicinal aerosol solution formulation product with improved chemical stability, comprising:
 - a cap;
 - a metering valve fitted in the cap;
 - a rubber valve gasket connected to the cap and or valve;
 - an aerosol canister connected to the cap, said aerosol canister further having an outwardly [[a]] rolled neck or full rollover rim in contact with said rubber valve gasket to reduce the compression of the gasket and thereby reduce the release of gasket rubber components; and
 - a pressurized medicinal aerosol solution formulation contained in said aerosol canister and in contact with said rubber gasket when in at least one of an inverted position and an upright position, said medicinal aerosol solution formulation comprising an active ingredient subject to a degradation by means of peroxides and/or other leachables from the gasket rubber, a hydrofluorocarbon propellant, a co-solvent, and optionally a low-volatility component.
- 2-5. (Cancelled)

6. (Original) The product of claim 1, wherein the valve is washed before crimping of the valve upon the canister with a pharmaceutically acceptable solvent.

7. (Original) The product of claim 1, wherein the valve is washed before crimping of the valve upon the canister with ethanol.

8. (Original) The product of claim 1, wherein the active ingredient is a corticosteroid.

9. (Original) The product of claim 8, wherein the corticosteroid is a 20-ketosteroid.

10. (Original) The product of claim 9, wherein the 20-ketosteroid is selected from the group consisting of budesonide and its epimers, mometasone furoate, triamcinolone acetonide, butixocort and ciclesonide.

11. (Original) The product according to claim 1, wherein the low-volatility component is selected from the group consisting of glycerol, propylene glycol, polyethylene glycol and isopropyl myristate.

12. (Original) The product according to claim 1, wherein the co-solvent is ethanol.

13. (Original) The product according to 1, wherein the propellant is selected from HFA 227, HFA 134a and their mixtures.

14. (Original) The product according to claim 1, wherein part or all of the internal surfaces of said canister consists of stainless steel, anodized aluminum or are lined with an inert organic coating.

15. (Original) The product according to claim 14, wherein the inert organic coating is perfluoroalkoxyalkane, perfluoroalkoxyalkylene, perfluoroalkylenes such as polytetrafluoroethylene, epoxy-phenol resin or fluorinated-ethylene-propylene, polyether sulfone, or their combinations.

16. (Original) The product according to claim 1, wherein part or all of the internal surfaces consist of anodized aluminum.

17. (Currently Amended) A process for making a chemically stable aerosol solution formulation product containing an active ingredient subject to a degradation by means of peroxides or other leachables, comprising the steps of:

forming a rolled neck or full rollover rim on a canister;

filling the canister with a pressurized aerosol solution formulation, said formulation comprising an active ingredient subject to a degradation by means of peroxides or other leachables; and

providing the canister with a valve having a rubber gasket as a component thereof, wherein the rounded edges of the canister prevent contact of a sharp edge with the rubber used as a valve gasket to reduce the compression of the gasket and thereby reduce the release of gasket rubber components, said pressurized aerosol solution formulation being in contact with said rubber gasket when in at least one of an inverted position and an upright position.

18. (Cancelled)

19. (Original) A process according to claim 17, further comprising the step of washing the valve with ethanol before attaching the valve to the canister.

20. (Original) The process according to claim 17, wherein part or all of the internal surfaces of said canister consists of stainless steel, anodized aluminum or are lined with an inert organic coating.

21. (Currently Amended) A process for the stabilization of an aerosol solution formulation containing an active ingredient subject to a degradation by means of peroxides or other leachables contained in a pressurized metered dose inhaler, comprising the steps of

providing a canister with a rolled neck or full rollover rim;

washing a valve provided with a rubber gasket for use in connection with said canister with ethanol prior to connecting said valve to said canister; and

contacting the rolled neck or full rollover rim with the rubber gasket of said valve to reduce the compression of the gasket and thereby reduce the release of gasket rubber components, and crimping said valve to said canister, said aerosol solution formulation being in contact with said gasket when in at least one of an inverted position and an upright position.

22-23. (Cancelled)

24. (Previously Presented) A product according to claim 1, wherein the cap is crimped to the canister, thereby forcing the gasket against said rim.

25. (Previously Presented) A process according to claim 17, wherein providing the canister with a valve comprises crimping the valve to the canister.

26. (Previously Presented) A process according to claim 21, wherein crimping said valve to said canister comprises crimping a cap associated with said valve to said canister.